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Date: July 28, 2009 Signature: _____ (Patricia M. Madhambayan)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	10/622,437
Confirmation No.:	4971
Filing Date:	July 18, 2003
Inventor(s):	Thomas J. FOGARTY et al.
Title:	EMBOLIZATION DEVICE AND A METHOD OF USING THE SAME
Examiner:	Katherine M. Dowe
Group Art Unit:	3734

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Washington, D.C. 22313-1450

APPEAL BRIEF

Sir:

This is an appeal brief to the final Office Action mailed October 28, 2008. Applicant submitted a Notice of Appeal on April 28, 2009 for which an appeal brief was due on June 28, 2009. Filed herewith is a Petition and fee for a one-month extension of time, thereby extending the deadline for response to July 28, 2009. Accordingly, this brief is timely filed.

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I. Real Party in Interest

This application is assigned to Thomas J. Fogarty of Portola Valley, California.

II. Related Appeals and Interferences

Assignee filed a Notice of Appeal in the following commonly assigned pending applications:

1) U.S. Patent Application 10/301,061, filed November 20, 2002, entitled DEVICES AND METHODS FOR TREATMENT OF VASCULAR ANEURYSMS. In response to Applicants' Appeal Brief of August 28, 2008, a Non-Final Office Action was issued, in which the Examiner withdrew the finality of the previous Final Office Action and indicated that the arguments filed in Applicant's August 28, 2008 Appeal Brief where fully considered and persuasive, resulting in the previous rejections being withdrawn.
2) U.S. Patent Application 10/293,139, filed November 12, 2002, entitled EMBOLIZATION DEVICE AND A METHOD OF USING THE SAME. In response to Applicants' Appeal Brief of May 19, 2008, a Notice of Allowability was mailed on September 19, 2008.

III. Status of Claims

Claims 1-38 were canceled. Claims 39-59 were rejected. Claims 39-59 are currently under appeal.

IV. Status of Amendment

No amendment was made subsequent to final rejection.

V. Summary of Claimed Subject Matter

The independent claims on appeal are Claims 39, 42 and 59. All noted specification locations, reference characters, and figures below are for exemplary purposes only and are non-limiting.

Claim 39 "a method for filling an abnormal void within the body, the method comprising," see e.g., figures 20 and 22; p. 23: ll. 19-23.

The claim recites attaching a first end of a first space-occupying element (28) of a space-occupying device (24) to a second end of a second space-occupying element (30) of the space-occupying device (24), (see e.g., figures 3a and 10; p. 5, l. 22 to p. 6, l. 2; p. 21, l. 18 to p. 22, l. 4). The claim also recites wherein the first end of the first space-occupying (28) device is rotatably attached to the second end of the second space-occupying device (30) (e.g., figures 3a and 10; p. 5, l. 22 to p. 6, l. 2; p. 13, ll. 1-4).

The claim also recites placing in a void (aneurysm 4) within the body a catheter (80) having a distal exit (82), the distal exit placed at a treatment site (sac 10), (see e.g., figure 20; p. 23, ll. 20-22).

The claim recites passing the first space-occupying element (28) through the catheter (80) and distal exit (82), (see e.g., figures 20; p. 7, ll. 19-21; p. 23, ll. 22-23). The claim recites, the space-occupying device (24) comprising a device volume, (see e.g., figures 10 and 20; p. 7, l. 21) and a coating wherein the coating comprises a binding agent (132), wherein the binding agent reduces the flexibility of the space-occupying device. (see e.g., figure 15; p. 17, ll. 10-13, 21-22; p. 24, ll. 17-19)

The claim also recites, passing the second space-occupying element (30) through the catheter (80) and distal exit (82) and deploying the device (24) into the treatment site (sac 10). (see e.g., figures 20; p. 7, ll. 19-21; p. 23, ll. 22-23).

Claim 42 "a method for filling an abnormal void within the body, the method comprising," see e.g., figures 20 and 22; p. 23: ll. 19-23.

The claim recites, coating a space-occupying device with a binding agent (132), wherein the binding agent is configured to reduce the flexibility of the space-occupying device, (see e.g., figure 15; p. 17, ll. 10-13, 21-22; p. 22, ll. 13-17; p. 24, ll. 17-19)

The claim recites attaching a first end of a first space-occupying element (28) of a space-occupying device (24) to a second end of a second space-occupying element (30) of the space-occupying device (24), (see e.g., figures 3a and 10; p. 5, l. 22 to p. 6, l. 2; p. 21, l. 18 to p. 22, l. 4). The claim also recites wherein the first end of the first space-occupying (28) device is rotatably attached to the second end of the second space-occupying device (30) (e.g., figures 3a and 10; p. 5, l. 22 to p. 6, l. 2; p. 13, ll. 1-4).

The claim also recites inserting the first space-occupying element (28) into the abnormal void (aneurysm 4) (see e.g., figures 20; p. 7, ll. 19-21; p. 23, ll. 22-23).

The claim recites "inserting the second space-occupying element (30) into the abnormal void (aneurysm 4) wherein the first space-occupying element (28) is rotatably attached to the second space-occupying element (30) (e.g., figures 3a and 10; p. 5, l. 22 to p. 6, l. 2; p. 13, ll. 1-4).

Claim 59 "a method for filling an abnormal void within the body, the method comprising," see e.g., figures 20 and 22; p. 23: ll. 19-23.

The claim recites attaching a first end of a first space-occupying element (28) of a space-occupying device (24) to a second end of a second space-occupying element (30) of the space-occupying device (24), (see e.g., figures 3a and 10; p. 5, l. 22 to p. 6, l. 2; p. 21, l. 18 to p. 22, l. 4). The claim also recites wherein the first end of the first space-occupying (28) device is rotatably attached to the second end of the second space-occupying device (30) (e.g., figures 3a and 10; p. 5, l. 22 to p. 6, l. 2; p. 13, ll. 1-4).

The claim recites, "wherein the first end of the first space-occupying device (24) is rotatable more than 180° with respect to the second end of the second space-occupying device" (See e.g., figure 3a)

The claim also recites placing in a void (aneurysm 4) within the body a catheter (80) having a distal exit (82), the distal exit placed at a treatment site (sac 10), (see e.g., figure 20; p. 23, ll. 20-22).

The claim recites passing the first space-occupying element (28) through the catheter (80) and distal exit (82), (see e.g., figures 20; p. 7, ll. 19-21; p. 23, ll. 22-23). The claim recites, the space-occupying device (24) comprising a device volume, (see e.g., figures 10 and 20; p. 7, l. 21) and a binding agent (132), wherein the binding agent reduces the flexibility of the space-occupying device. (see e.g., figure 15; p. 17, ll. 10-13, 21-22; p. 24, ll. 17-19)

The claim also recites, passing the second space-occupying element (30) through the catheter (80) and distal exit (82) and deploying the device (24) into the treatment site (sac 10). (see e.g., figures 20; p. 7, ll. 19-21; p. 23, ll. 22-23).

VI. Grounds of Rejection to be Reviewed on Appeal

Whether claims 39-59 are unpatentable under 35 U.S.C. 103(a), over Berenstein et al., (U.S. Pat. No. 6,458,119) in view of Ritchart (U.S. Pat. No. 4,994,069).

VII. Argument

A. Rejections under 35 U.S.C. §103(a) over Berenstein et al., (U.S. Pat. No. 6,458,119) in view of Ritchart (U.S. Pat. No. 4,994,069)

Claims 39-41

The Office Action rejected claims 39-41 under 35 U.S.C. §103(a) as allegedly being unpatentable under 35 U.S.C. 103(a), over Berenstein et al., (U.S. Pat. No. 6,458,119) in view of Ritchart (U.S. Pat. No. 4,994,069)." Applicants submit that the Office Action fails to establish a proper prima facie case of obviousness over claims 39-41.

MPEP §2142 states that "[r]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.'" KSR. 550 U.S. 398, 82 USPQ2d at 1396 quoting In re Kahn, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)." Additionally, if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. In re Gordon, 221 USPQ 125; MPEP §2143.01(V).

Applicants' Claim 39 recites "a method for filling an abnormal void within the body" where the method requires the step of "passing the first space-occupying element through the catheter and distal exit, the space-occupying device comprising a device volume and a coating wherein the coating comprises a binding agent, wherein the binding agent reduces the flexibility of the space-occupying device."

The Final Office Action alleges that Berenstein discloses the claimed invention through its disclosure of "a method of filling an aneurysm by placing a catheter into the aneurysm and injecting a vasoocclusive coil into the aneurysm. The coil consists of chain links as shown in fig. 6B which are the claimed elements and which are rotatable relative to each other. Also, a binding agent 602 would cause the chain coil to exhibit less flexibility compared to if it were not present." (OA at ¶ 4).

The Office Action goes on to state: "Berenstein does not disclose the binding agent is a coating. Ritchart discloses a similar space-occupying device having a coating

comprising a binding agent 36. Ritchart teaches the binding agent is a rigid water soluble material (col 5, lines 62-68). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the device of Berenstein such that a majority of the device comprised a coating comprising the binding agent in order to cover a greater area of the device with a binding agent to keep the coil relatively straight during its expulsion from the lumen of the catheter. Furthermore, a dissolvable coating as taught by Ritchart is advantageous since it allows the binding agent to dissolve once placed in the aneurysm due to its water solubility." (OA at ¶ 4).

Applicants disagree for the following reasons:

Berenstein (Fig. 6B), relied on by the Office Action, discloses a chain (600) "having suitable polymeric filaments (602) such as Dacron, cotton, or other materials tied to the chain. Organic fibers such as silk, Dacron, or cotton provide a ready substrate for clot formation in the interior region of a vessel. The FIG. 6B fibers (602) are looped from spot to spot on the chain." Col. 7, ll. 26-32. Contrary to the assertions made in the Office Action, Berenstein's fibers (602) used for clot formation, clearly do not disclose "a binding agent, wherein the binding agent reduces the flexibility of the space-occupying device."

In assuming that the fibers (602) disclose a binding agent (without a coating), the Office Action alleges that it would have been obvious to modify the chain (600) having fibers (602) with the coating taught by Ritchart to satisfy the elements of Claim 39, "to cover a greater area of the device with a binding agent to keep the coil relatively straight during its expulsion from the lumen of the catheter," and "to increase the rigidity of the device to simplify the delivery process." (OA at ¶ 4 & 7).

Ritchart, however, discloses a vaso-occlusion wire having a wall "coated with a rigid, water-soluble material 36, as seen in the cross sectional view in FIG. 4B....which can be applied to the interior wire region and dehydrated, as by reduced pressure, to form a rigid shell within the wire coil." Col. 5, l. 62 to Col. 6, l. 5. Accordingly, the Office Action's reasoning for combining the teachings of Berenstein and Ritchart is flawed because one of two situations would exist if the coating of Ritchart were combined with the chain (600) of Berenstein: (1) the water-soluble material 36 would not be activated (i.e., dehydrated to form a rigid shell) in the delivery catheter, thereby providing no effect to

keep the chain (600) with fibers (602) relatively straight during its expulsion from the lumen of a catheter or to increase the rigidity of the device to simplify the delivery process; or (2) the water-soluble material 36 would be active in the catheter pre-deployment, in which case the "rigid shell" would make the chain (600) more rigid while in the catheter and reduce the ability of the chain (600) with fibers (602) to navigate the naturally tortuous configuration of the deployed catheter and the available anatomical void into which it is being deployed. This would defeat the stated benefits of the Berenstein device achieved from its highly flexible nature. (See Berenstein, Col. 3, ll. 27-28; "because of their (the devices) flexibility and size, there is little opportunity for friction to develop with the catheter lumen."). Thus, the Office Action fails to provide rational reasoning to support its conclusion of obviousness, and the proposed modification would render the cited art invention being modified unsatisfactory for its intended purpose.

The Office Action also alleges that it would have been obvious to modify the chain (600) with fibers (602) of Berenstein with the coated rigid, water-soluble material 36 taught by Ritchart to satisfy the elements of Claim 39 because "a dissolvable coating as taught by Ritchart is advantageous since it allows the binding agent to dissolve once placed in the aneurysm due to its water solubility." (OA at ¶4).

Applicants submit that this reasoning for combining the cited references is also flawed. First, assuming for argument's sake that the fiber (602) is a binding agent, the binding agent is either water soluble or water insoluble. Modifying the fiber (602) of Berenstein with the water-soluble material 36 coating of Ritchart would not alter the inherent properties of the fiber (602) and allow it to dissolve, i.e., if the fiber is water insoluble, applying the water-soluble Ritchart coating would not change the inherent solubility properties of the fiber.

Second, the present claim recites a binding agent, "wherein the binding agent reduces the flexibility of the space-occupying device." The specification also describes the binding agent as providing a structural reinforcement. P. 13, l. 20-23. Thus, the purpose of the binding agent is not to dissolve in water, but to reduce the flexibility of the space-occupying device. This is exactly the opposite of having the binding agent dissolve and float away.

Third, if the goal were to create a device that would allow the binding agent to dissolve once placed in the aneurysm, a binding agent in the form of fibers (602) would actually have improved and faster dissolvability compared to a binding agent in the form of a coating. The fibers would dissolve faster and better than a coating because fluid would be able to come into contact with all sides of the fibers compared with a coating which would only be exposed to fluid on one side since it would be attached to the remainder of the device (e.g., chain 600) on its other side. Also contributing to the fibers improved dissolvability is the fibers' higher surface area to volume ratio compared with a coating. Thus a person of skill in the art seeking to create a device having a dissolvable binding agent would not have been motivated to modify a binding agent in the form of a fiber with that of a coating.

Therefore, the Office Action again fails to provide rational reasoning to support its conclusion of obviousness. Thus, it would not have been obvious to one of skill in the art seeking a dissolvable binding agent to substitute the fiber of Berenstein with the coating of Ritchart based on the reasons provided in the Office Action. Applicants respectfully submit that combining the coating of Ritchart with the device of Berenstein would not have been obvious to one having ordinary skill in the art.

Thus, Applicants submit that the Office Action fails to establish a proper prima facie case of obviousness with respect to claim 39. Furthermore, Claims 40-41 are dependent from Claim 39 and are not obvious over the cited art for at least the same reasons as independent claim 39.

In view of the above, Applicants request withdrawal of this rejection.

Claims 42-58

The Office Action rejected claims 42-58 under 35 U.S.C. §103(a) as allegedly being unpatentable under 35 U.S.C. 103(a), over Berenstein et al., (U.S. Pat. No. 6,458,119) in view of Ritchart (U.S. Pat. No. 4,994,069)."

Applicants submit that the Office Action fails to establish a proper prima facie case of obviousness over claims 42-58.

Applicants' Claim 42 recites "a method for filling an abnormal void within the body" where the method requires the step of "coating a space-occupying device with a binding agent, wherein the binding agent is configured to reduce the flexibility of the space-occupying device."

For at least the reasons discussed above, with respect to claims 39-41, Applicants respectfully submit that combining the coating of Ritchart with the device of Berenstein would not have been obvious to one having ordinary skill in the art. Thus, Applicants submit that the Office Action fails to establish a proper prima facie case of obviousness with respect to claim 42. Furthermore, Claims 43-58 are dependent from Claim 42 and are not obvious over the cited art for at least the same reasons as independent claim 42.

In view of the above, Applicants request withdrawal of this rejection.

Claim 59

The Office Action rejected claims 59 under 35 U.S.C. §103(a) as allegedly being unpatentable under 35 U.S.C. 103(a), over Berenstein et al., (U.S. Pat. No. 6,458,119) in view of Ritchart (U.S. Pat. No. 4.994,069)."

Applicants submit that the Office Action fails to establish a proper prima facie case of obviousness over claim 59.

Applicants' Claim 59 recites "a method for filling an abnormal void within the body" where the method requires the step of "passing the first space-occupying element through the catheter and distal exit, the space-occupying device comprising a device volume and a binding agent, wherein the binding agent reduces the flexibility of the space-occupying device."

For at least the reasons discussed above, with respect to claims 39-58, Applicants respectfully submit that combining the teachings of Ritchart with the device of Berenstein would not have been obvious to one having ordinary skill in the art. Thus, Applicants submit that the Office Action fails to establish a proper prima facie case of obviousness with respect to claim 59.

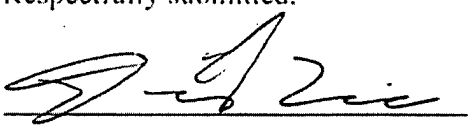
In view of the above, Applicants request withdrawal of this rejection.

B. Summary

Applicant believes all outstanding issues raised in the previous Office Action are addressed herein and that the claims are in condition for allowance.

In the event the appropriate fee and/or petition is not filed herewith and the U.S. Patent and Trademark Office determines that an extension and/or other relief is required. Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with this filing to **Deposit Account No. 50-3973** referencing Attorney Docket No. **FGRTNZ00200**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted.



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VIII. Claims Appendix

1. -38. (Canceled).

39. A method for filling an abnormal void within the body, the method comprising:

attaching a first end of a first space-occupying element of a space-occupying device to a second end of a second space-occupying element of the space-occupying device, wherein the first end of the first space-occupying device is rotatably attached to the second end of the second space-occupying device;

placing in a void within the body a catheter having a distal exit, the distal exit placed at a treatment site;

passing the first space-occupying element through the catheter and distal exit, the space-occupying device comprising a device volume and a coating wherein the coating comprises a binding agent, wherein the binding agent reduces the flexibility of the space-occupying device;

passing the second space-occupying element through the catheter and distal exit, and deploying the device into the treatment site.

40. The method of Claim 39, wherein the flexibility of the space-occupying device increases when the binding agent is exposed to a softening agent.

41. The method of Claim 39, wherein deploying comprises exposing the device to a softening agent.

42. A method for filling an abnormal void within the body, the method comprising:

coating a space-occupying device with a binding agent, wherein the binding agent is configured to reduce the flexibility of the space-occupying device,

attaching a first end of a first space-occupying element of a space-occupying device to a second end of a second space-occupying element of the space-occupying device, wherein the first end of the first space-occupying device is rotatably attached to the second end of the second space-occupying device;

inserting the first space-occupying element into the abnormal void,

inserting the second space-occupying element into the abnormal void, wherein the first space-occupying element is rotatably attached to the second space-occupying element.

43. The method of Claim 42, wherein the flexibility of the space-occupying device increases when the binding agent is exposed to a softening agent.

44. The method of Claim 42, wherein inserting a first space-occupying element comprises exposing the device to a softening agent.

45. The method of Claim 43, wherein the binding agent is exposed to the softening agent before the inserting of the first space-occupying element into the abnormal void.

46. The method of Claim 41, wherein the binding agent is exposed to the softening agent before the passing the first space-occupying element through the distal exit.

47. The method of Claim 39, further comprising imaging the abnormal void, and then sizing the space-occupying device according to the imaging of the abnormal void.

48. The method of Claim 47, wherein sizing comprises reducing the size of the space-occupying device before passing the first space-occupying element through the distal exit.

49. The method of Claim 39, further comprising inducing clot formation on the space-occupying device.

50. The method of Claim 39, wherein inducing clot formation comprises wherein the coating comprises a thrombogenic material.

51. The method of Claim 39, wherein the first space-occupying element is discrete from the second space-occupying element.

52. The method of Claim 39, wherein the first space-occupying element is integrated with the second space-occupying element.

53. The method of Claim 42, further comprising imaging the abnormal void, and then sizing the space-occupying device according to the imaging of the abnormal void.

54. The method of Claim 53, wherein sizing comprises reducing the size of the space-occupying device before inserting the first space-occupying element.

55. The method of Claim 42, further comprising inducing clot formation on the space-occupying device.

56. The method of Claim 42, wherein inducing clot formation comprises applying on the space-occupying device a coating comprising a thrombogenic material.

57. The method of Claim 42, wherein the first space-occupying element is discrete from the second space-occupying element.

58. The method of Claim 42, wherein the first space-occupying element is integrated with the second space-occupying element.

59. A method for filling an abnormal void within the body, the method comprising:

attaching a first end of a first space-occupying element of a space-occupying device to a second end of a second space-occupying element of the space-occupying device, wherein the first end of the first space-occupying device is rotatably attached to the second end of the second space-occupying device, wherein the first end of the first space-occupying device is rotatable more than 180° with respect to the second end of the second space-occupying device;

placing in a void within the body a catheter having a distal exit, the distal exit placed at a treatment site;

passing the first space-occupying element through the catheter and distal exit, the space-occupying device comprising a device volume and a binding agent, wherein the binding agent reduces the flexibility of the space-occupying device;

passing the second space-occupying element through the catheter and distal exit, and

deploying the device into the treatment site.

Evidence Appendix

None.

IX. Related Proceedings Appendix

None.